



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Gary W. Zlotnick

Divisional Application of:

Serial No.: 08/469,842

Filed: June 6, 1995

Title: Preparation and Uses of LOS-Depleted Outer Membrane Proteins of Gram-Negative Cocci

Date: <u>3/5/02</u> EXPRESS MAIL LABEL NO. <u>EL928149956 US</u>

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
P.O. Box 2327
Arlington, VA 22202

Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)

☒ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☐ under 37 CFR 1.97(c) together with either:
☐ a Statement under 37 CFR 1.97(e), as checked below, or
☐ a \$180.00 fee under 37 CFR 1.17(p), or
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:
☐ a Statement under 37 CFR 1.97(e), as checked below, and
☐ a \$180.00 fee under 37 CFR 1.17(p), or
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
- ☒ Copies of the cited references are enclosed.
- ☐ Copies of cited references are enclosed except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
- ☒ Some of the listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☒ The "concise explanation" requirement (non-English references) for reference AL2 under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
- ☐ the explanation provided in the Specification.
- ☐ submission of the enclosed International Search Report.
- ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
- ☒ the enclosed English language abstract cited as reference AV.

☐ Applicant requests that the following non-published pending applications be considered:

Examiner's
Initials

____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

Examiner

Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Lisa M. Treannie
Lisa M. Treannie
Registration No.: 41,368
Telephone: (978) 341-0036
Facsimile: (978) 341-0136

Concord, MA 01742-9133

Dated:

3/5/02

PTO-1449 REPRODUCED

INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

March 5, 2002

(Use several sheets if necessary)

ATTORNEY DOCKET NO.
1646.1013-022

APPLICATION NO.

APPLICANT
Gary W. Zlotnick

FILING DATE

GROUP



U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA	4,271,147	6/2/81	Helting, et al.	424	92	
	AB	4,601,903	7/22/86	Frasch	424	92	
	AC	4,707,543	11/17/87	Zollinger, et al.	530	402	
	AD	5,601,831	2/11/97	Green, et al.	424	256.1	
	AE	4,386,066	5/31/1983	O'Rourke, et al.	424	92	
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	AL	WO 90/06696 ✓	28-JUN-90	PCT			
	AM	0 182 401 ✓	28-MAY-86	EPO			
	AN	WO 93/03761 ✓	4-MAR-93	PCT			
	AO	0 301 992 ✓	1-FEB-89	EPO			
	AP	0 073 169 ✓	2-MAR-83	EPO			
	AQ	0 351 604 ✓	24-JAN-90	EPO			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AR	Beuvery, E.C. et al., "Preparation and Physicochemical and Immunological Characterization of Polysaccharide-Outer Membrane Protein Complexes of <i>Neisseria meningitidis</i> ," <i>Infection and Immunity</i> , 40(1):369-380 (1983).
AS	Wedge, E. et al., "Restoration of Antibody Binding to Blotted Meningococcal Outer Membrane Proteins Using Various Detergents," <i>J. Immunol. Methods</i> , 113:51-59 (1988).
AT	Zlotnick, G.W. et al., "Purification and Characterization of a Peptidoglycan-Associated Lipoprotein from <i>Haemophilus influenzae</i> ," <i>J. Biol. Chem.</i> , 263(20):9790-9794 (1988).

EXAMINER

DATE CONSIDERED

PTO-1449 REPRODUCED

ATTORNEY DOCKET NO.
1646.1013-022

APPLICATION NO.

INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

March 5, 2002

(Use several sheets if necessary)

APPLICANT
Gary W. Zlotnick

FILING DATE

GROUP

U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	AL2	3516017 A1 ✓	27-NOV-86	DE			X
	AM2	0 090 660 ✓	05-OCT-83	EPO			
	AN2	90/13032 ✓	01-NOV-90	PCT			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AU	✓	Poolman, J.T. et al., "Comparison of Meningococcal Outer Membrane Protein Vaccines Solubilized with Detergent or C Polysaccharide," <i>Antonie van Leeuwenhoek J. of Microbiology</i> , 53(6):413-419 (1987).
AV	✓	Kittel, J., "Isolation of Proteins from Biological Membranes by Solubilisation With Limited Amount of Detergent," (1994) <i>Derwent Info. Ltd.</i> (WPI Acc No.: C86-138270) (Abstract : DE 3516017).
AW	✓	Helenius, A. and Simons, K., "Solubilization of Membranes by Detergents," <i>Biochimica et Biophysica Acta</i> , 415:29-79 (1975).
AX	✓	Moriyon, I. and Berman, D.T., "Effects of Nonionic, Ionic, and Dipolar Ionic Detergents and EDTA on the <i>Brucella</i> Cell Envelope," <i>J. Bacteriology</i> , 152(2):822-828 (1982).
AY	✓	Murphy, T.F. and Bartos, L.C., "Surface-Exposed and Antigenically Conserved Determinants of Outer Membrane Proteins of <i>Branhamella catarrhalis</i> ," <i>Infection and Immunity</i> , 57(10):2938-2941 (1989).

EXAMINER

DATE CONSIDERED

PTO-1449 REPRODUCED

ATTORNEY DOCKET NO.
1646.1013-022

APPLICATION NO.

INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

March 5, 2002

(Use several sheets if necessary)

APPLICANT
Gary W. Zlotnick

FILING DATE

GROUP

U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AZ	✓	"Other Species of Neisseria and Related Genera" In <i>Davis Microbiology</i> , 3rd; Gotschlich, E.C., ed., <u>The Niesseriae</u> , Chapter 30, pages 643-644.
AR2	✓	Mandrell, R.E. and Zollinger, W.D. "Human Immune Response to Meningococcal Outer Membrane Protein Epitopes after Natural Infection or Vaccination," <i>Infect. Immun.</i> , 57:1590-1598 (1989).
AS2	✓	Frasch, C.E. and Peppler, M.S., "Protection Against Group B <i>Neisseria meningitidis</i> Disease: Preparation of Soluble Protein and Protein-Polysaccharide Immunogens," <i>Infection and Immunity</i> , 37(1):271-280 (1982).
AT2	✓	"Centocor Stops Trials of Flagship Drug," <i>The Washington Post</i> , page D3, January 19, 1993.
AU2	✓	Spalding, B.J., "In Shocking Synergen, Sepsis Tallies Third Victim," <i>Bio/Technology</i> , 11:428-429 (1993).
AV2	✓	Peppler, M.S. and Frasc, C.E., "Protection Against Group B <i>Neisseria meningitidis</i> Disease, Effect of Serogroup B Polysaccharide and Polymyxin B Immunogenicity of Serotype Protein Preparations," <i>Infection and Immunity</i> , 37:264-270 (1982).
AW2	✓	Collins, M.L.P. and Salton, M.R.J., "Preparation and Crossed Immuno-electrophoretic Analysis of Cytoplasmic and Outer Membrane Fractions from <i>Neisseria gonorrhoeae</i> ," <i>Infection and Immunity</i> , 30(1):281-288 (1980).
AX2	✓	Mandrell, R.E. and Zollinger, W.D., "Use of a Zwitterionic Detergent for the Restoration of the Antibody-Binding Capacity of Electroblooded Meningococcal Outer Membrane Proteins," <i>J. Immunol. Methods</i> , 67:1-11 (1984).

EXAMINER

DATE CONSIDERED

PTO-1449 REPRODUCED

INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

March 5, 2002

(Use several sheets if necessary)

ATTORNEY DOCKET NO.
1646.1013-022

APPLICATION NO.

APPLICANT
Gary W. Zlotnick

FILING DATE

GROUP

U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AY2	✓	Catlin, B.W., "Branhamaceae New Family a Proposed Family to Accommodate the Genera Branhamella and Moraxella," <i>Int'l. J. Systematic Bact.</i> , 41(2):320-323 (1991) (Abstract only).
AZ2	✓	Saukkonen, K. et al., "Protective Efficacy of Monoclonal Antibodies to Class 1 and Class 3 Outer Membrane Proteins of <i>Neisseria meningitidis</i> B:15:P1.16 in Infant Rat Infection Model: New Prospects for Vaccine Development," <i>Microbial Pathogenesis</i> , 3:261-267 (1987).
AR3	✓	Schnaitman, C.A., "Effect of Ethylenediaminetetraacetic Acid, Triton X-100, and Lysozyme on the Morphology and Chemical Composition of Isolated Cell Walls of <i>Escherichia coli</i> ," <i>J. Bacteriology</i> , 108(1):553-563 (1971).
AS3	✓	Frasch, C.E. and Gotschlich, E.C., "An Outer Membrane Protein of <i>Neisseria meningitidis</i> Group B Responsible for Serotype Specificity," <i>J. Exper. Medicine</i> , 140:87-104 (1974).
AT3	✓	Campagnari, A.A., et al., "Lipooligosaccharide Epitope Shared Among Gram-Negative Non-Enteric Mucosal Pathogens," <i>Microb Pathology</i> , 8:353-362 (1990).
AU3	✓	Smyth, C.J., et al., "Immunology of Outer Membrane Proteins of Gram-Negative Bacteria", <i>Immunology of the Bacterial Cell Envelope</i> , Chapter 7: 177-201 (1995).
AV3	✓	Frasch, C.E., et al., "New Developments in Meningococcal Vaccines", <i>Meningococcal Protein Vaccines</i> , 633-639 (1985).

EXAMINER

DATE CONSIDERED